

K964152

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UniCAP Total IgE 510(k) Submission
Section 11. Summary of Safety and Effectiveness

11. **SUMMARY OF SAFETY AND EFFECTIVENESS**

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990).

Date of Summary Preparation: October 10 , 1996

Distributor: Pharmacia & Upjohn

Manufacturer: Pharmacia AB
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Device Names: UniCAP Total IgE Fluoroimmunoassay
Pharmacia Total IgE Control LMH

Common Name: *In vitro* quantitative assay for the measurement of circulating total IgE.

Classification:

<u>Product Name</u>	<u>Product Code</u>	<u>Class</u>	<u>CFR</u>
UniCAP Total IgE Fluoroimmunoassay	82DGC	II	866.5510
Pharmacia Total IgE Control LMH	82DGC	II	866.5510

Substantial Equivalence to:

Assay:

Pharmacia CAP System IgE FEIA

Control Sera:

Phadexact Serum Total IgE Controls, Low, Medium, High

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Intended Use Statements:

1. UniCAP Total IgE Fluorimmunoassay is an *in vitro* assay for the quantitative measurement of circulating total IgE in human serum or plasma. UniCAP Total IgE assay is to be used with the instrument UniCAP 100. It is intended for *in vitro* diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other clinical findings, and is to be used in clinical laboratories, as well as, physician office laboratories.
2. Pharmacia Total IgE Control LMH is intended for laboratory use in monitoring the performance of total IgE measurements as determined by Phadebas IgE PRIST /Phadezym IgE PRIST, Pharmacia IgE RIA, Pharmacia IgE RIAC, Pharmacia CAP System IgE RIA/FEIA and UniCAP Total IgE.

General Description:

UniCAP is a fully integrated and automated system for the determination of total IgE in human blood serum or plasma. The UniCAP system includes the UniCAP 100 instrument with software for immunodiagnostic testing; UniCAP RM External Software; UniCAP reagents, in this submission reagents for the measurement of total IgE, and Pharmacia Total IgE Control LMH.

The UniCAP 100 instrument is designed to handle all steps from sample and reagent handling to processing of results. Reagents, requests, samples and ImmunoCAP are loaded into the instrument and the process, which takes 2.5 hours is started. A laboratory report is automatically printed when the process is ended.

UniCAP 100 can store a calibration curve to be used for up to one month. After an initial calibration curve is accepted by the software, subsequent assay runs may use the stored calibration curve for calculation of results. In these runs, Curve Controls are included to validate that the run is on the same response level as the stored curve. Limits for the response of the Curve Controls are defined in the UniCAP 100 Operator and Panel Software. A new calibration curve is run once a month, and/or when a new lot number of Total IgE Conjugate or Anti- IgE ImmunoCAP is introduced.

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Device Comparison:

UniCAP Total IgE Fluoroimmunoassay reagents when used with the UniCAP 100 Instrument are substantially equivalent to another commercially available assay and instrumentation system for the measurement of total IgE, namely Pharmacia CAP System IgE FEIA used with Pharmacia CAP System instrumentation.

Comparison Data:

Comparison studies were performed to establish the substantial equivalence of results using UniCAP 100 and UniCAP Total IgE Assay compared to the corresponding instrumentation and reagents in Pharmacia CAP System.

The comparison study comprised 150 serum samples with concentrations spread over the complete measuring range of the assay. Linear regression analysis gives the equation $y = 24.5 + 1.05 x$, where y represents UniCAP and x represents Pharmacia CAP System. The correlation coefficient is 0.99.

Therefore, Pharmacia & Upjohn concludes that the two systems show excellent correlation, and are substantially equivalent.